

Package leaflet: information for the user

Levofloxacin 5 mg/ml solution for infusion levofloxacin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levofloxacin 5 mg/ml is and what it is used for
2. What you need to know before you are given Levofloxacin 5 mg/ml
3. How Levofloxacin 5 mg/ml is given
4. Possible side effects
5. How to store Levofloxacin 5 mg/ml
6. Contents of the pack and other information

1. What Levofloxacin 5 mg/ml is and what it is used for

The name of your medicine is Levofloxacin 5 mg/ml solution for infusion. Levofloxacin belongs to a group of medicines called antibiotics. Levofloxacin is a “quinolone” antibiotic. It works by killing the bacteria that cause infections in your body.

Levofloxacin is used to treat infections of the:

- Lungs, in people with pneumonia
- Urinary tract, including your kidneys or bladder
- Prostate gland, where you have a long lasting infection
- Skin and underneath the skin, including muscles. This is sometimes called “soft tissue”.

In some special situations, levofloxacin may be used to lessen the chances of getting a pulmonary disease named anthrax or worsening of the disease after you are exposed to the bacteria causing anthrax.

2. What you need to know before you are given Levofloxacin 5 mg/ml

Do not have this medicine and tell your doctor if:

- You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin ciprofloxacin or ofloxacin or any of the ingredients of this medicine (listed in section 6)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have ever had epilepsy
- You have ever had tendon problems such as tendinitis that was related to treatment with a “quinolone antibiotic”. A tendon is a cord that joins your muscle to your skeleton
- You are a child or a growing teenager
- You are pregnant, might become pregnant, or think you may be pregnant
- You are breast-feeding

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you are given this medicine.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you have your medicine if:

- You are 60 years of age or older
- You are using corticosteroids, sometimes called steroids (see section "Other medicines and Levofloxacin 5 mg/ml")
- You have ever had a fit (seizure)
- You have had damage to your brain due to a stroke or other brain injury
- You have kidney problems
- You have something known as 'glucose – 6 – phosphate dehydrogenase deficiency'. You are more likely to have serious problems with your blood when taking this medicine
- You have ever had mental health problems
- You have ever had heart problems: caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section "Other medicines and Levofloxacin 5 mg/ml").
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given this medicine.

Other medicines and Levofloxacin 5 mg/ml

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This is because levofloxacin can affect the way some other medicines work. Also some medicines can affect the way levofloxacin works.

In particular, tell your doctor if you are taking any of the following medicines. This is because it can increase the chance of you getting side effects, when taken with levofloxacin:

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or rupture of your tendons.
- Warfarin - used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Theophylline - used for breathing problems. You are more likely to have a fit (seizure) if taken with levofloxacin.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen, indomethacin. You are more likely to have a fit (seizure) if taken with levofloxacin.
- Ciclosporin - used after organ transplants. You may be more likely to get the side effects of ciclosporin.
- Medicines known to affect the way your heart beats. This includes medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine), for psychiatric disorders (antipsychotics), and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin).

- Probenecid – used for gout and cimetidine – used for ulcers and heartburn. Special care should be taken when taking either of these medicines with levofloxacin. If you have kidney problems, your doctor may want to give you a lower dose.

Urine tests for opiates

Urine tests may show ‘false-positive’ results for strong painkillers called ‘opiates’ in people having Levofloxacin 5 mg/ml. If your doctor has prescribed a urine test, tell your doctor you are having Levofloxacin 5 mg/ml.

Tuberculosis tests

This medicine may cause “false negative” results for some tests used in laboratory to search for the bacteria causing tuberculosis.

Pregnancy and breastfeeding

Do not have this medicine if:

- You are pregnant, might become pregnant or think that you may be pregnant
- You are breastfeeding or planning to breast-feed

Driving and using machines

You may get side effects after taking this medicine, including feeling dizzy, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

Levofloxacin 5 mg/ml contains sodium chloride (salt).

This medicine contains 3.5 mg of sodium per ml of infusion (a total of 177.1 mg sodium in 50 ml and 354.2 mg sodium in 100 ml). This should be taken into consideration by patients on a controlled sodium diet.

3. How Levofloxacin 5 mg/ml is given

How Levofloxacin 5 mg/ml is given

- Levofloxacin 5 mg/ml is a medicine for use in hospitals
- It will be given to you by a doctor or nurse as an injection. The injection will be into one of your veins, and be given over a period of time (this is called an intravenous injection).
- For 250 mg of Levofloxacin 5 mg/ml, the infusion time should be 30 minutes or more
- For 500 mg of Levofloxacin 5 mg/ml, the infusion time should be 60 minutes or more.
- Your heart rate and blood pressure should be closely monitored. This is because an unusual fast beating of the heart and a temporary lowering of blood pressure are possible side effects that have been seen during the infusion of a similar antibiotic. If your blood pressure drops noticeably while you are being given the infusion, it will be stopped straight away.

How much Levofloxacin 5 mg/ml is given:

If you are not sure why you are being given this medicine or have any questions about how much of this medicine is being given to you, speak to your doctor, nurse or pharmacist.

- Your doctor will decide on how much Levofloxacin 5 mg/ml you should have
- The dose will depend on the type of infection you have and where the infection is in your body
- The length of your treatment will depend on how serious your infection is

Adults and elderly

- *Pneumonia* : 500 mg, once or twice daily
- *Infection of urinary tract, including your kidneys and bladder*: 500 mg once daily
- *Prostate gland infection*: 500 mg, once daily.

- *Infections of the skin and underneath the skin, including muscles:* 500 mg once or twice daily.

Adults and the elderly with kidney problems

Your doctor may need to give you a lower dose.

Children and teenagers

This medicine must not be given to children or teenagers.

Protect your skin from sunlight

Keep out of direct sunlight while having this medicine and for 2 days after you stop having it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs
- Avoid sun beds

If you are given more Levofloxacin 5 mg/ml than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine.

Having too much Levofloxacin 5 mg/ml may cause the following effects to happen: convulsive fits (seizures), feeling confused, dizzy, less conscious, having tremors and heart problems – leading to uneven heart beats as well as feeling sick (nausea).

If you miss a dose of Levofloxacin 5 mg/ml

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you stop having Levofloxacin 5 mg/ml

Your doctor or nurse will continue giving you this medicine, even if you feel better. If it is stopped too soon, your condition may get worse or the bacteria may become resistant to the medicine. After a few days treatment with the solution for infusion, your doctor may decide to switch you to the tablet form of this medicine to complete your course of treatment.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Stop having Levofloxacin 5 mg/ml and tell a doctor or nurse straight away if you notice the following side effect:

Very rare (may affect up to 1 in 10,000 people)

- You may have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Stop having Levofloxacin 5 mg/ml and tell a doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent treatment:

Rare (may affect up to 1 in 1,000 people)

- Watery diarrhoea which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem
- Pain and inflammation in your tendons or ligaments which could lead to rupture. The Achilles tendon is affected most often
- Fits (convulsions)

Very rare (may affect up to 1 in 10,000 people)

- Burning, tingling, pain or numbness. These may be signs of something called “neuropathy”

Other:

- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals
- Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking this medicine, consult an eye specialist immediately.

Tell your doctor is any of the following side effects gets serious or lasts longer than a few days:

Common (may affect up to 1 in 10 people)

- Sleeping problems
- Headache, feeling dizzy
- Feeling sick (nausea, vomiting) and diarrhoea
- Increase in the level of some liver enzymes in your blood
- Reactions at the site of infusion
- Inflammation of a vein

Uncommon (may affect up to 1 in 100 people):

- Changes in the number of other bacteria or fungi, infection by fungi named Candida, which may need to be treated
- Changes in the number of white blood cells shown up in the results of some blood tests (leukopenia, eosinophilia)
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo)
- Shortness of breath (dyspnoea)
- Changes in the way things taste, loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation
- Itching and skin rash, severe itching or hives (urticaria), sweating too much (hyperhidrosis)
- Joint pain or muscle pain
- Blood test may show unusual results due to liver (bilirubin increased) or kidney (creatinine increased) problems
- General weakness.

Rare (may affect up to 1 in 1,000 people):

- Bruising and bleeding easily due to a lowering in the number of blood platelets (thrombocytopenia)
- Low number of white blood cells (neutropenia)
- Exaggerated immune response (hypersensitivity)
- Lowering of your blood sugar levels (hypoglycaemia). This is important for people that have diabetes.
- Seeing or hearing things that are not there (hallucinations, paranoia), change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions
- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- Tingly feeling in your hands and feet (paraesthesia)
- Problems with your hearing (tinnitus) or eyesight (blurred vision)

- Unusual fast beating of your heart (tachycardia) or low blood pressure (hypotension)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system).
- Changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis.
- Fever

Other side effects include:

- Lowering in red blood cells (anaemia): this can make the skin pale or yellow due to damage of the red blood cells; lowering in the number of all types of blood cells (pancytopenia)
- Fever, sore throat and a general feeling of being unwell that does not go away. This may be due to a lowering in the number of white blood cells (agranulocytosis).
- Loss of circulation (anaphylactic like shock)
- Increase of your blood sugar levels (hyperglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes.
- Changes in the way things smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision
- Impairment or loss of hearing
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm including cardiac arrest, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
- Difficulty breathing or wheezing (bronchospasm)
- Allergic lung reactions
- Pancreatitis
- Inflammation of the liver (hepatitis)
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Inflammation of the vessels that carry blood around your body due to an allergic reaction (vasculitis)
- Inflammation of the tissue inside the mouth (stomatitis)
- Muscle rupture and muscle destruction (rhabdomyolysis)
- Joint redness and swelling (arthritis)
- Pain, including pain in the back, chest and extremities
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
- Persistent headache with or without blurred vision (benign intracranial hypertension)

Reporting of side effects

If you get any of side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levofloxacin 5 mg/ml

- Keep this medicine out of the sight and reach of children.
- It should be kept in its outer carton in order to protect from light until use.
- Your doctor or nurse will ensure that your medicine is properly stored.
- There is an expiry date on the carton after EXP, your doctor or nurse will check that this date has not passed. The expiry date refers to the last day of the month.

6. Contents of the pack and other information

What Levofloxacin 5 mg/ml contains

- the active substance (the ingredient that makes this medicine work) is levofloxacin, as levofloxacin hemihydrate.
- Each ml of solution for infusion contains 5 mg of levofloxacin
- Each 100 ml of solution for infusion contains 500 mg of levofloxacin.
- Each 50 ml of solution for infusion contains 250 mg of levofloxacin.
- the other ingredients are:
 - sodium chloride,
 - hydrochloric acid (for pH adjustment)
 - sodium hydroxide (for pH adjustment)
 - water for injections

What Levofloxacin looks like and contents of the pack

Levofloxacin 5 mg/ml solution for infusion is a clear greenish-yellow solution free from particles.

It is supplied in a 100 ml plastic bag containing 100 ml or 50 ml of solution for infusion. Packs of 1, 5 and 20 bags are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Farmaprojects, S.A.U.
Santa Eulàlia 240-242,
08902 L'Hospitalet de Llobregat,
Barcelona, España

Manufacturer

Polpharma, S.A.
83-200 Starogard Gdanski
Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom:	Levofloxacin 5 mg/ml, solution for infusion
Ireland:	Levofloxacin 5 mg/ml, solution for infusion
Poland:	Levofloxacin FP
Hungary:	Levofloxacin Farmaprojects 5 mg/ml, Oldatos infúzió
Germany:	Levofloxacin Eberth 5 mg/ml, Infusionslösung
Spain:	Levofloxacin Accord 5 mg/ml, solución para perfusión EFG

This leaflet was last revised in (MM/YYYY)

To be completed nationally

Other sources of information

Detailed information on this medicine is available on the web site of (MA/Agency)

The following information is intended for healthcare staff only:

Handling instructions

Preparation for administration:

1. Inspect the bag before use. It must only be used if the solution is a clear, greenish- yellow solution, practically free from particles.
2. Hold the plastic bag with the connection ports uppermost.
3. Twist off the protection cap from the connection port
4. Insert the piercing pin of the i.v. set into the connection port with a twisting motion.
5. Suspend the bag from the hanger

See the carton box of the product for diagram

Method of administration

The solution for infusion is ready for use, and should only be administered by **slow** infusion into a vein. The infusion time should **not be less than 30 minutes** for 250 mg (50 ml) and **not be less than 60 minutes** (1 hour) for 500 mg (100 ml) of levofloxacin solution for infusion. Protection from light is not necessary during infusion time.

Special warnings and precautions for use:

Infusion Time

The recommended infusion time of at least 30 minutes for 250 mg or 60 minutes for 500 mg Levofloxacin 5 mg/ml solution for infusion should be observed. It is known for ofloxacin, that during infusion tachycardia and a temporary decrease in blood pressure may develop. In rare cases, as a consequence of a profound drop in blood pressure, circulatory collapse may occur. Should a conspicuous drop in blood pressure occur during infusion of levofloxacin, (L-isomer of ofloxacin) the infusion must be halted immediately.

Dosage in patients with kidney impairment

	250 mg/24 h	500 mg/24 h	500 mg/12 h
Creatinine clearance	first dose	first dose	first dose
50-20 ml/min	250 mg	500 mg	500 mg
	<i>then:</i>	<i>then:</i>	<i>then:</i>
	125 mg/24 h	250 mg/24 h	250 mg/12 h
19-10 ml/min	<i>then:</i>	<i>then:</i>	<i>then:</i>
	125 mg /48 h	125 mg/24 h	125 mg/12 h
< 10 ml/min (including hemodialysis and CAPD) ¹	<i>then:</i>	<i>then:</i>	<i>then:</i>
	125 mg/48 h	125 mg/24 h	125 mg/24 h

¹ No additional doses are required after haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

Shelf life:

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Keep the bag in its outer carton in order to protect from light. The shelf life of the product after removal of the bag from the outer carton is 24 hours when stored under indoor light conditions. Chemical and physical in-use stability has been demonstrated for 8 hours at 25°C upon further dilution of the product with compatible solutions.

From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

For single use only. Discard any unused solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

Compatibilities:

This medicine may be given alone or with one of the following solutions:

sodium chloride 9 mg/ml (0.9%),

glucose 50 mg/ml (5%),

glucose 25 mg/ml (2.5%) in Ringer's solution,

Incompatibilities:

This medicine should not be mixed with herapin or alkaline solutions (e.g. sodium hydrogen carbonate).

This medicine must not be mixed with other medicinal products except those mentioned in the section above.